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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MILLER, MARINA I	
ART UNIT	**PAPER NUMBER**
1631	

DATE MAILED: 08/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/924,340	BEJANIN ET AL.	
	Examiner	Art Unit	
	Cheyne D. Ly	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 May 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *34-40 and 47-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *34-40 and 47-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Search Result 24*.

5.0-0

DETAILED ACTION

1. Applicants' arguments filed May 23, 2005 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

2. The new title has been accepted.

3. Claims 34-40 and 47-49, SEQ ID NO. 58, are examined on the merits.

CLAIM REJECTIONS - 35 U.S.C. § 112, SECOND PARAGRAPH

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 37, 40, and 49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. The instant rejection has been necessitated by claim amendments.

7. Claim 37 recites the limitation of "at least six consecutive amino acids...spans positions 92 and 98" causes said claim to be vague and indefinite. For example, are the "at least six consecutive amino acids" within positions 97 and 98? Or the "at least six consecutive amino acids" start at position 97 or 98? Clarification of the metes and bounds is require. Claims 40 and 49 are rejected for being dependent from claim 37.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 37, 40, and 49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. NEW MATTER.

10. The instant rejection has been necessitated by claim amendments.

11. The limitation of "fragment spans positions 92 and 98 of SEQ ID NO. 58" has not been found in the instant specification.

LACK OF UTILITY UNDER 35 U.S.C. § 101

12. The pending claims have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. 112, first paragraph, "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

13. The examiner is using the following definitions in evaluating the claims for utility.

"Specific" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

14. Claims 34-40 and 47-49 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility.

15. This rejection is maintained with respect to claims 34-40 and 47-49, as recited in the previous office action mailed November 30, 2004.

RESPONSE TO ARGUMENTS

16. On page 13, Applicant argues the claimed polypeptide "has utility for the diagnosis of diseases or disorders associated with abnormalities of the metabolism of collagen..."

Applicant's argument is not persuasive because the instant specification does not provide any specific or substantial support for the asserted utility as discussed below.

17. Applicant points to paragraph [0983] of the published application to argue "the claimed polypeptide can be used as an injectable biomaterial or in cosmetic compositions..." It is noted the pointed to support is located in paragraph [0895] of the published application. Further, Applicant's argument is not persuasive because nowhere in the specification does Applicant provide substantial or specific support for the argued asserted utility. For example, Applicant points to the specification to argue that the invention is useful for preparing cosmetic compositions such as skin creams with anti-wrinkle activity. However, Applicant does not provide substantial or specific support which correlates the claimed polypeptide with the asserted activity such as anti-wrinkle activity. As discussed in the previous Office Action, the asserted utilities in paragraph [0895] are non-specific uses that are applicable to a large family of structurally related collagen related proteins, however, not particular or specific to the polypeptide being claimed.

18. Applicant points to paragraph [0972] to argue "the claimed variant of the human alpha 1 type XVI collagen contains two collagen triple helix repeat domains...", therefore, has utility. It is noted the pointed to support is located in paragraph [0884] of the published application. The disclosure in the instant specification has been noted. However, Applicant's assertion is based on sequence similarity, and sequence similarity alone does not support that the claimed polypeptide has specific or substantial utility. Therefore, Applicant

has not provided evidence that one of ordinary skill in the art would have recognized that the identified specific and substantial utility was well-established at the time of filing.

BASIS FOR REJECTION

19. The critical limitation of claims 34-40 and 47-49 are the polypeptide of the sequence describe in SEQ ID NO: 58. Applicant discloses that cDNA of SEQ ID NO. 57, which encodes the polypeptide of SEQ ID NO. 58, is a novel splice variant of the human alpha 1 type XVI collagen gene (GB M92642.1). From the sequence similarities between the sequence SEQ ID NO. 57 and the sequence of accession number M92642, Applicant concludes that the claimed polypeptide is a variant of the human alpha 1 type XVI collagen gene. Applicant asserts that said conclusion supports the asserted patentable utility of the claimed polypeptide as directed to collagen related diseases (pages 214-218).

20. For example, the specification states that the polypeptide sequences may be useful for an *in vitro* assay to various proteases which degrade or denature collagen, in animal models, diagnose diseases or disorders associated with abnormalities of the metabolism of collagen or the monitoring of collagen degradation etc. (pages 214-218). The above-mentioned list of desirable utility for the claimed sequence falls short of a readily available utility. These are non-specific uses that are applicable to a large family of structurally related collagen related proteins, however, not particular or specific to the polypeptide being claimed.

21. It is noted that Pan et al. describes the isolation of the cDNA sequence with the accession number of GB M92642.1, and attributes said sequence as the human alpha 1 type XVI collagen gene by chromosomal location analysis and sequence alignment (Pan et al., Abstract etc. and page 6567-6568, Results §). Pan et al. concludes that the "structural similarities

between the α1(XVI) collagen and the FACIT group raise the intriguing possibility that the α1(XVI) collagen may serve similar functions" (Pan et al., page 6569, column 1, last paragraph). Pan et al. does not provide any data beyond the isolation and sequence alignment that would specifically support that the human alpha 1 type XVI collagen gene is responsible for any collagen related diseases as asserted by Applicant. Applicant's disclosure of sequence similarities between the sequence SEQ ID NO. 57 and the sequence of GB M92642.1 only supports that the claimed polypeptide has an "intriguing possibility" of having similar functions as the FACIT proteins. Therefore, the specification does not provide any specific support for the asserted patentable utility of the claimed polypeptide as directed to collagen related diseases.

22. Further, the claimed polypeptide is not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. It is noted that the instant specification discloses the isolation and studying of the claimed polypeptide. However, the identifying and studying the properties of a protein itself or the mechanisms in which the protein is involved, such as the polypeptide sequence of SEQ ID NO: 58, does not define a "real world" context for use. Similarly, the other listed utilities and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to many such compounds in the large family of structurally related of collagen proteins.

CLAIMS REJECTED UNDER U.S.C. § 112, FIRST PARAGRAPH

23. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

LACK OF ENABLEMENT

24. Claims 34-40 and 47-49 are rejected under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the claimed sequence.

25. This rejection is maintained with respect to claims 34-40 and 47-49, as recited in the previous office action mailed November 30, 2004.

RESPONSE TO ARGUMENT

26. Applicant's directed to the utility of the claimed invention has been addressed above.

BASIS FOR REJECTION

27. The claimed invention is not supported by a specific, substantial, and credible utility or a well-established utility for the reasons set forth above (refer to 35 U.S.C. § 101 rejection), one skilled in the art would not know how to use the claimed invention.

CLAIM REJECTIONS - 35 USC § 102

28. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

29. Claims 37, 40, and 49 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Olsen et al. (1999).

30. The instant rejection has been necessitated by claim amendments.

31. Olsen et al. discloses a collagen polypeptide fragment comprising at least six consecutive amino acids which spans positions 92 and 98 of SEQ ID NO:58 (See Search Result 24), as in instant claims 37 and 40.

32. The polypeptide has been cloned into an expression vector (page 15, lines 5-21), represents a physiologically acceptable carrier of claim 49.

CONCLUSION

33. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

34. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

35. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547. The USPTO's official fax number is (571) 273-8300.

36. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

37. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

38. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (571) 272-0716. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

39. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718.

C. Dune Ly /cdl
8/4/05

Ardin H. Marschel 8/5/05
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER